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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,577

08/22/2005

Klaus Godl

JCLA 16061

8370

7590

02/08/2008

J.C. Patents
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EXAMINER

BRADLEY, CHRISTINA

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

02/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,577	Applicant(s) GODL ET AL.	
	Examiner Christina Marchetti Bradley	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-94 is/are pending in the application.
- 4a) Of the above claim(s) 51,52,59-71,76-89,92 and 93 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-58,72-75,90,91 and 94 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 51-94 are pending; claims 51, 52, 59-71, 76-89, 92 and 93 are withdrawn for pertaining to a non-elected invention. In the reply filed 10/27/2006, Applicant elected the species 6-(3-amino-propoxy)-7-methoxy-quinazoline-4-yl]-(3-chloro-4-fluoro-phenyl)-amine.

Claim Rejections - 35 USC § 112

2. Applicant's arguments, filed 9/25/2007, have been fully considered and are persuasive. The rejection of claims 53-58, 72-75, 90 and 91 under 35 U.S.C. 112, second paragraph, has been withdrawn.

Claim Rejections - 35 USC § 103

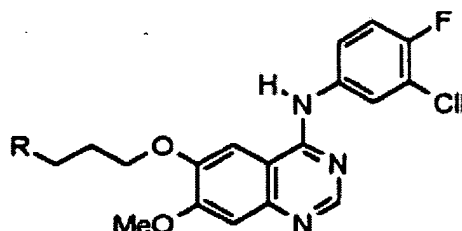
3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 53, 57, 58, 72-74, 90, 91 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barker *et al.* (*Biorg. Med. Chem. Lett.*, **2001**, 11, 1911-4) in view of Knockaert *et al.* (*Chem. & Bio.*, **2000**, 7, 411-22, cited in Office Action mailed 1/05/2007).

Barker *et al.* teach an inhibitor of the epidermal growth factor receptor tyrosine kinase, an ATP-binding protein, with the following structure:



where R can be a variety of amine ligands including Me₂N (compounds 27-32, Table 2). With the exception of R, this compound belongs to the genus represented by formula V and is identical to the elected species 6-(3-amino-propoxy)-7-methoxy-quinazoline-4-yl]-(3-chloro-4-fluoro-phenyl)-amine. In the elected species, R is NH₂. In the prior art compound, R is NMe₂. With respect to formula V, A is at position 6 and is O, n is 3, l is 0, m is 0; R₁ is at position 7 and is O, l is 1, p is 1, R₁ is H; and Xa is NH, l is 0, l is 0, l is 0, o is 0 and R₁ is a phenyl substituted with Cl and F.

5. Barker *et al.* do not teach the conjugation of this inhibitor to a solid support and its use as a medium for separating ATP binding proteins from a pool of proteins.
6. Knockaert *et al.* teach the conjugation of chemical inhibitors of cyclin-dependent kinases to solid supports and the use of the immobilized inhibitors to separate proteins that bind to the inhibitors from cell extracts.
7. It would have been obvious to one of ordinary skill in the art to immobilize the epidermal growth factor receptor tyrosine kinase inhibitor taught by Barker *et al.* according to the method taught by Knockaert *et al.* and to use the resulting immobilized inhibitor to separate kinases that bind to this inhibitor from a pool of proteins. With respect to the group R, it would have been

obvious to replace it with NH_2 because the linker group in the compound taught by Knockaert *et al.* is terminated with an NH group covalently linked to the agarose bead.

8. The skilled artisan would have been motivated to immobilize the epidermal growth factor receptor tyrosine kinase inhibitor taught by Barker *et al.* given that Knockaert *et al.* teaches that the affinity purification approach can isolate a small set of highly purified kinases and can be used as a general method for identifying intracellular targets relevant to a particular class of ligands (abstract). Knockaert *et al.* state (page 420) “knowledge of the pattern of target proteins allows for a better interpretation of the cellular effects of inhibitors and will also help in orienting the optimization of compounds for therapeutic applications against cancer...” The epidermal growth factor receptor tyrosine kinase inhibitor taught by Barker *et al.* is a potential agent for treating cancer. Thus, the skilled artisan would be motivated to investigate intracellular targets of this compound. There would have been a reasonable expectation of success given that the synthesis of the inhibitor is taught by Barker *et al.* and the conjugation chemistry is taught by Knockaert *et al.*

9. All limitations of claims 90, 91 and 94 are satisfied. With respect to claim 53, the solid support used by Kockaert *et al.* is agarose. With respect to claim 57, the pool used by Knockaert *et al.* was a cell extract from a variety of cell types and organisms (abstract). With respect to claim 58, the ATP binding protein taught by Barker *et al.* is a kinase. With respect to claims 72-74, it would have been obvious to use the immobilized inhibitor in suitable buffer conditions.

10. Claims 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barker *et al.* (*Biorg. Med. Chem. Lett.*, **2001**, *11*, 1911-4) and Knockaert *et al.* (*Chem. & Bio.*, **2000**, *7*, 411-22), as applied to claims 90, 53, 57, 58, 72-74, 91 and 94 above, in further view of

Lochmuller *et al.* (*Separation Sci. Tech.*, **1987**, 22, 2111-26, cited in Office Action mailed 1/05/2007). Lochmuller *et al.* teach the use of ferromagnetic beads in affinity chromatography (abstract). It would have been obvious to use the magnetic beads taught by Lochmuller *et al.* in place of the agarose beads taught by Knockaert *et al.* because the beads can be easily separated from the liquid phase by simply applying a magnet. It would have been further obvious to optimize the parameters of the beads for the affinity chromatography application.

11. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Marchetti Bradley whose telephone number is (571) 272-9044. The examiner can normally be reached on Monday, Tuesday and Thursday, 8 A.M. to 5:30 P.M.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Marchetti Bradley, Ph.D.
Patent Examiner
Art Unit 1654

cmb

